

**REMARKS**

The inventor of the present application, Jiro Hitomi, filed the application as Applicant and has again attached hereto a Supplemental Declaration declaring that he is the inventor of this application and of parent application serial number 09/270,455. Applicant further attests to the fact that he has reviewed the SEQ ID's submitted with this and the parent application and has verified that SEQ ID NO:19 correspond directly to SEQ ID NO: 1 as identified in the application as originally filed, and corresponds to SEQ ID NO: 19 in the Amendment dated March 7, 2007.

The statement of the Examiner regarding so-called "added material" not being supported by the original disclosure is inconsistent with the Declaration signed by Applicant. Applicant has already pointed out that there were some inconsistencies in a prior Amendments filed in November 2006. To overcome this inconsistency, Applicant has submitted a Declaration attesting to this fact. The Applicant has stated that the Amendment on March 7, 2007 is not a departure from the specification and claims as originally filed SEQ ID NO: 19 (<sup>17</sup>Gln) is correct and Applicant is attesting to this as being correct. This is also consistent with Figure 1, which is not in error and is consistent with the Amendment filed on March 7, 2007. Applicant has not added a new sequence for SEQ ID NO: 19. Accordingly, there is a 1:1 correspondence between SEQ ID NO: 1 and SEQ ID NO: 19 and no

discrepancy exists with Fig. 1 and the patented SEQ ID NO: 19 in U.S. Patent No. 5,976,832.

Applicant wishes to further point out that the present application claims priority from Application Serial No. 08/568,310, now U.S. Patent 5,976,832. SEQ ID NO:19 in USP 5,976,832 has been found to be both novel and non-obvious. Moreover, USP 5,976,832 was involved in an Interference before the Board of Patent Interferences, No. 105,501, in 2006 and a clean copy of the sequence listing for SEQ ID NO:19 as submitted in the Interference is attached hereto as further corroborating evidence that the listing for SEQ ID NO: 19 in the subject application as filed is identical to the sequence listing of SEQ ID NO: 19 in the priority application Serial No. 08/568,310.

Since Applicant in his Declaration and as set forth in the clean copy of the sequence listing for parent application Serial No. 08/568,310 involved in patent interference 105,501 clearly shows a match between SEQ ID NO:19 of the subject application as originally filed, and between SEQ ID NO: 19 of the priority application, no additional corroborating evidence is believed necessary to overcome the objection to the specification under 35 USC 132. No evidence other than the Declaration filed by Applicant and the clean copy of the sequence listing from the patent interference 105,501, as attached hereto, need to be presented to corroborate the accuracy of the sequence listing for SEQ ID NO: 19.

The rejection of claims 22-23 under 35 USC 112, first paragraph, as containing subject matter not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed, has possession of the claimed invention is respectfully traversed. This rejection is based on an allegation by the Examiner that SEQ ID NO:19 contains <sup>17</sup>Glu, which is not in the original SEQ ID NO:19 (<sup>17</sup>Gln). As explained earlier, the original SEQ ID NO:19 (<sup>17</sup>Gln) is identical to that as originally filed and also corresponds to SEQ ID NO:1. Applicant is attesting to the original listing of SEQ ID NO: 19. Accordingly, no departure exists in the phrase SEQ ID NO: 19 claimed in claims 22-23 and its original lineage.

There is no newly-added SEQ ID NO: 19 and the original SEQ ID NO: 19 (<sup>17</sup> Gln) is supported by the original specification. Applicant is not claiming or asserting that a new SEQ ID NO: 19 exists with (<sup>17</sup>Glu). Accordingly, the Examiner should withdraw the allegation of “new matter”.

The rejection of Claims 22-23 under 35 USC 102(b) as being anticipated by Guignard et al (European Journal of clinical Investigation, Vol.:24, Supl. 2, pp. 211 (1994) as evidenced by Guignard et al July 1995 and/or anticipated by Kelly et al. (J.Patho 1989) as evidenced by Guignard et al. (Feb. 1996), is respectfully traversed.

The Examiner has pointed out that generally in S100 protein an

antibody having cross-reactivity can be easily obtained as is evidenced by Guignard (1996) "that the similarities among the S100 family proteins make the generation of specific anti-sera difficult due to structural conservation and might explain the cross-reactivity of Mac 387 with MRP-14, MRP-8 and P6."

However, according to Fig. 1D in Kosaki et al, J. Clin, Endocrinol. Metab., 89(1), p. 5423-5428, monoclonal antibodies hCF128 and hCF113 against human CAAF1, are different from Mac387 and do not react with MRP-14 and MRP-8 and therefore, it is considered that they specifically react with human CAAF1.

As can be seen from the above, monoclonal antibodies which specifically react with CAAF1 can be obtained. Since reagents using these antibodies are specific to CAAF1, they are useful for studying physiological properties of CAAF1. Claims 22 and 23 now limit the antibody to "a monoclonal antibody" and are novel. Clearly, since polyclonal antibodies have cross-reactivity, the rejection under 35 USC 102 should be withdrawn for this reason alone.

In addition to the foregoing and as explained earlier in the Preliminary Amendment filed with the RCE, there is no teaching in the cited references of an antibody which is specific to a calcium-binding protein comprising amino acid sequence shown in SEQ ID NO:19.

Nowhere is there any teaching of a nucleic acid or amino acid sequence in Guignard or Kelly nor has the Examiner made any allegation that any of

the cited references teach an antibody specific to a calcium-binding protein comprising amino acid sequence shown by SEQ ID NO: 19. Both of these references describe the antibodies and proteins, but nowhere is there any mention of the antibodies specific to the respective sequences. The Examiner uses Yamamura to help support this argument, and while it is not being relied on for the actual anticipation rejection, the reference itself is from 1996. Applicant points out that this application claims priority to its parent which issued as USP 5,976,832 and was filed on December 6, 1995, which ultimately claims priority to JP 7-045564 and JP 7-070468, which were filed on March 6, 1995. Therefore, Applicant believes that Yamamura cannot be used as a reference under this section of the statute.

Moreover, SEQ ID No. 19 has already been found to be both novel and non-obvious as evidenced by US Patent No. 5,976,832, shown to be patentably distinctive even from SEQ ID NO: 20. Applicant is attaching a copy of a Declaration filed in Patent Interference no. 105,501 entitled "Second Weber Declaration", which explains why SEQ ID NO: 19 is both novel and non-obvious. In fact, this Declaration from the prior Interference shows why the "possibility" alleged by the Examiner to support obviousness of the claims clearly does not provide any basis to support obviousness.

The rejection of claims 22-23 under 35 USC 103(a) as being unpatentable over Dell'Angelica et al (JPC 269(46): 2829-28936 1994) as evidenced by the specification disclosure on page 40, lines 6-9, Bost et al, is respectfully

traversed.

As the Examiner has pointed out, since 21 amino acid residues of N-terminal are homologous between SEQ ID NO: 19 and Calgranulin and total homologous is 80%, therefore, there is a possibility that obtainable antibodies have cross-reactivity between SEQ ID NO:19 and Calgranulin C. This does not provide a basis for alleging obviousness since immunogens are different, monoclonal antibody specifically reactive to one of SEQ ID NO:19 and Calgranulin can be obtained.

SEQ 19 TKLEDHLEGIINTFHQYSVRVGHFDTLNKRELKQLITKELPKTLQNTKDQP

Cal C -----L—Y—I-----N-K-----G

TIDKIFQDLADKDGAVSFEEFVVLVSRVLKTAHIDIHKE

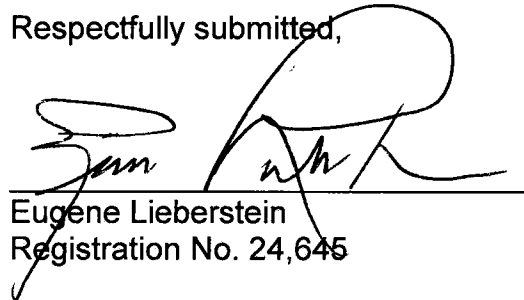
-----N-----NA-EQ--K-----TF—I---DN-----

Claims 22 and 23, as amended, specify a monoclonal antibody specific to calcium-binding protein comprising an amino acid sequence, as shown in SEQ ID NO:19. Accordingly, for the reasons given above and in light of the Declaration filed in the Interference, as attached hereto, the present invention is clearly novel and inventive and the rejection of claims 22-23 under 35 USC 103(a) should be withdrawn.

**CONCLUSION**

Reconsideration and allowance of claims 22-23 is respectfully solicited.

Respectfully submitted,



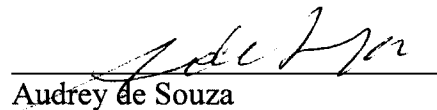
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Dated: September 8, 2009

CUSTOMER NO.: 79681

**CERTIFICATE OF TRANSMISSION**

I hereby certify that this Amendment w/attachments is being deposited via EFS-Web addressed to Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450 on September 8, 2009



Audrey de Souza